


Division of
Immunization Services



WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES



VACCINE SAFETY AND CURRENT ISSUES IN IMMUNIZATION

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Why is Vaccine Safety increasing in Importance?

As disease risks decrease, attention on vaccine risks increase

- Public confidence in vaccine safety is critical
- Higher than ever standard of safety for vaccines
- Vaccines generally healthy vs. consumers of other pharmaceuticals

Why is Vaccine Safety Increasing in Importance?

- Vaccinations universally recommended and mandated
- Lower risk tolerance means adverse reactions must be investigated thoroughly



Post licensure Surveillance

- Identify rare reactions
- Monitor increases in known reactions
- Identify risk factors for reactions
- Identify vaccine lots with unusual rates or types of events
- Identify signals



Vaccine Adverse Event Reporting System (VAERS)

- Passive reporting system administered by the CDC and FDA
- Receives approximately 15,000 reports per year
- Must be reported to the BPH, Division of Immunization Services if state-supplied vaccine used or if administered in an LHD



VAERS

- VAERS detects
 - New or rare events
 - Increases in rates of known side effects
 - Patient risk factors
- VAERS signals confirmed through additional studies
- Not all reported vaccine reactions causally related to vaccine

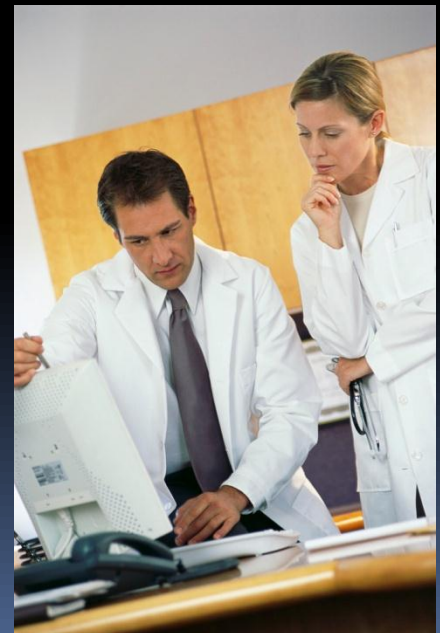
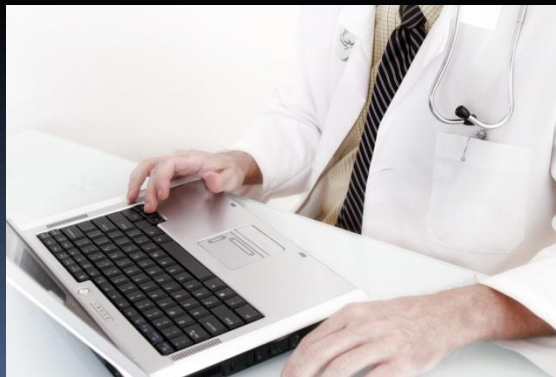
Classification of VAEs

- Vaccine-induced
- Vaccine-potentiated
- Programmatic Error (Provider's Role)
- Coincidental



Vaccine Safety Data link Program

- Large database which links vaccination and health records
- An active surveillance system
- Populated by 10 HMOs, roughly 2% of the U.S. population
- Crucial to vaccine safety monitoring



Vaccine Injury Compensation Program

- Created in 1986 by the National Childhood Vaccine Injury Act
- “No fault” program
- Covers all routinely recommended childhood vaccines
- Basis of the Vaccine Injury Table

Role of the Provider

- Store and administer vaccines properly
- Adhere to guidelines for timing and spacing of vaccines
- Observation of contraindications and precautions
- Management of side effects
- Report suspected VAEs to VAERS
- Communicate vaccine benefits/risks



Contraindication vs. Precaution

- Contraindication: A condition in a recipient that **increases** the chance of a serious adverse event
- Precaution: A condition that **might** increase the chance or severity of an adverse event or compromise the ability of the vaccine to produce immunity



Contraindications and Precautions

- Only two conditions are considered permanent contraindications to vaccination:
 - **Severe (anaphylactic) allergic reaction** to a vaccine component or following a prior dose of vaccine
 - **Encephalopathy** not due to another identifiable cause within 7 days of vaccination

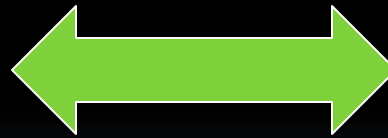


Contraindications and Precautions

- Two temporary contraindications to vaccination with *live* vaccines:

* Pregnancy

* Immunosuppression



Contraindications and Precautions

- Two conditions are temporary *precautions* to vaccination:
 - * Moderate or severe acute illness (all vaccines)
 - * Recent receipt of an antibody- containing blood product (MMR and Varicella only)
- Fever: ≥ 100.4 = moderate or severe

Invalid Contraindications



- Minor illness
- Mild/moderate local reaction or fever following a prior dose
- Disease exposure or convalescence
- Pregnancy or immunosuppression in the household
- Antimicrobial therapy



Invalid Contraindications



- Premature birth
- Breastfeeding
- Allergies to products not in the vaccine
- Family history (unrelated to immunosuppression)
- *possibility that a family history of seizures could warrant a *precaution* to MMRV

Benefit and Risk Communications

- Providers should ask questions regarding any possible adverse reactions associated with previous vaccination(s)
- Opportunities for questions from recipient should be provided
- Vaccine information statements (VISs) must be provided before each dose of vaccine



What's New in Immunization?

- 64CSR95 (Interpretive Rule)
- PCV₁₃
- MMRV
- Rotavirus and Intussusception
- Data

64CSR95

- Tdap and MCV₄ vaccines will become requirements for 7th grade entry
- MCV₄ booster dose will be required at 12th grade entry
- 39 states and D.C. require a Td/Tdap dose for middle school
- WV will become the 11th state to require MCV₄ vaccine

PCV 13

- Children in mid-series of PCV7 should start receiving PCV13 instead
- Booster doses for children who completed PCV7 series:
 - < 59 months and healthy
 - 6-18 years at increased risk may receive one dose.




MMRV Vaccine

- Combined MMR & Varicella
- Slightly higher risk of febrile seizure w/ 1st dose
- ACIP expresses *no preference* between MMR/VAR and MMRV for 1st dose
- ACIP continues to *recommend* MMRV for 2nd dose
- Rare situation when family history may be considered as a precaution – (seizures)






Rotavirus

- Study in Mexico: 1.8 fold increase in intussusception 1-7 days after dose 1 of Rotarix vaccine
 - No increase found in Brazil for Rotarix
 - In the U.S.: No increase identified for either Rotarix or Rotateq (VSD). However, studies of the VSD or Merck data can rule out a slight increased risk
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Rotavirus

- Pre-Vaccine
 - 400,000 doctor visits
 - 200,000 ER visits
 - 70,000 hospitalizations
 - 20-60 deaths
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Rotavirus

- Now
- 85% decrease in rotavirus hospitalizations since vaccine was reintroduced
- As of 2008, 40,000- 60,000 fewer cases of rotavirus in the U.S. than in the pre-vaccine era.
- Recommendations unchanged

Data – 2 Year Olds

| | <u>U.S.</u> | <u>W.V.</u> |
|--------------------------|--------------|--------------|
| 4:3:1:0:3:1:4* | 70.5% | 60.9% |
| Hep B (birth) | 60.8% | 53.7% |
| Hep A | 46.6% | 51.7% |
| Influenza (1) | 41.5% | 39.2% |
| Influenza (fully) | 24.7% | 24.1% |

4 DTaP, 3 Polio, 1 MMR, 0 Hib, 3 Hep B,
1 Varicella and 4 PCV

Data - Teens

| | <u>U.S.</u> | <u>W.V.</u> |
|------------------------|--------------|--------------|
| Td or Tdap | 76.2% | 52.2% |
| Tdap | 55.6% | 40.5% |
| MCV ₄ | 53.6% | 39.0% |
| HPV (3 doses) * | 26.7% | 27.0% |

Sample: 13-17 year olds

* Females only

Data – Adult Influenza

Influenza

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|--------------|-------|
| Age 19-49 HR | 33.4% |
|--------------|-------|

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| Age 19-49 Non-HR | 19.7% |
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| Age 50-64 HR | 51.5% |
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| Age 50-64 Non-HR | 34.2% |
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| Age 65 and older | 65.6% |
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| HCP (any age) | 52.4% |
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Questions ?

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